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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,966	11/17/1999	RODERICK L. HALL	98.736-A	5234

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/441,966	HALL ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 15-21 is/are pending in the application.
- 4a) Of the above claim(s) 18,20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10,15-17 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>02/07/00, 09/22/00</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Application***

- [1]** Claims 1-10 and 15-21 are pending in the application.
- [2]** Applicants' amendment to the claims, filed June 22, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3]** Receipt of a terminal disclaimer, filed June 22, 2004, is acknowledged.
- [4]** All references cited in the information disclosure statements (IDSs) filed February 07, 2000 and September 22, 2000 have been considered by the examiner. A copy of each IDS is attached to the instant Office action.
- [5]** Applicant's arguments filed June 22, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [6]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.
- [7]** Newly submitted claims 18, 20, and 21 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The elected invention of Group XVI is drawn to a method for accelerating the rate of mucociliary clearance in a subject using the polypeptide of SEQ ID NO:8. Claim 18 has been amended such that the claim no longer reads on the elected invention. Similarly, newly added claims 20-21 do not read on the elected invention. The claims are directed

to inventions that are independent or distinct for those reasons stated in the Office action mailed April 02, 2002.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18, 20, and 21 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

**[8]** Claims 1-10, 15-17, and 19 are being examined only to the extent the claims read on the elected subject matter, i.e., a method for accelerating the rate of mucociliary clearance using SEQ ID NO:8.

#### ***Sequence Compliance***

**[9]** As stated in a previous Office action, in a transmittal letter filed September 09, 2002, it is noted that applicants state that a computer readable form (CRF) of the amended sequence listing has been submitted. However, the CRF of the sequence listing has not been received and/or entered. Applicants are requested to re-submit a CRF of the sequence listing and include a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d).

#### ***Specification/Informalities***

[10] The specification remains objected to in the use of trademarks. The use of trademarks has been noted in this application (see, e.g., page 10, line 34 and all other instances in the specification). All trademarks disclosed in the specification should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 112, Second Paragraph***

[11] In view of applicants' amendment to limit claim 18 to a non-elected invention, the rejection of claim 18 under 35 U.S.C. 112, second paragraph, as set forth in item [11] of the Office action mailed is withdrawn.

***Claim Rejections - 35 USC § 112, First Paragraph***

[12] In view of applicants' amendment to claims 1 and 15 to limit the Kunitz-type serine protease inhibitor to SEQ ID NO:8 and amendment to claim 18 to limit the claim to a non-elected invention, the written description rejection of claims 1-10 and 15-18 under 35 U.S.C. 112, first paragraph, as set forth in item [12] of the Office action mailed October 03, 2003 is withdrawn.

[13] In view of applicants' amendment to claims 1 and 15 to limit the Kunitz-type serine protease inhibitor to SEQ ID NO:8 and amendment to claim 18 to limit the claim to a non-elected invention, the scope of enablement rejection of claims 1-10 and 15-18

under 35 U.S.C. 112, first paragraph, as set forth in item [13] of the Office action mailed October 03, 2003 is withdrawn.

***Claim Rejections - 35 USC § 103***

**[14]** The rejection of claims 1-10, 15-17, and 19 under 35 U.S.C. 103(a) as being unpatentable over Tamburini et al. in view of Rasche et al. and O'Riordan et al. is maintained for the reasons of record as set forth in item [14] of the Office action mailed October 03, 2003 and for the reasons stated below.

**[15]** RESPONSE TO ARGUMENTS: Applicants argue the cited references, alone or in combination, do not teach the use of the specific serine protease inhibitors as shown in amended claim 1. Applicants' argument is not found persuasive.

As stated in a previous Office action, Tamburini et al. teach a Kunitz-type serine protease inhibitor that is identical to SEQ ID NO:8 of the instant application (page 7) including a Kunitz-type serine protease inhibitor having at least one of the disulfide bonds as recited in claim 19 (see, e.g., page 35, top). The combination of references teaches all limitations of the claims and provides a motivation and a reasonable expectation of success for practicing the claimed invention. Consequently, the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention.

***Double Patenting Rejection(s)***

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[16] In view of applicants' submission of a terminal disclaimer and amendment to claim 18 to limit the claim to a non-elected invention, the provisional obviousness-type double patenting rejection of claims 1-10 and 15-18 over claims 1-10 and 15-18 of co-pending Application 09/218,913 is withdrawn.

### ***Conclusion***

[17] Status of claims:

- Claims 1-10 and 15-21 are pending.
- Claims 18 and 20-21 are withdrawn from consideration as being drawn to a non-elected invention.
- Claims 1-10, 15-17, and 19 are rejected.
- No claim is in condition for allowance.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:00 am to 3:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding

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should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.  
Patent Examiner  
Art Unit 1652

*DS 07-07-04*